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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/771,585

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Louis J. Dietz

SURR1 8/D

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03/09/2006

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EXAMINER

EDWARDS, PATRICK L

ART UNIT

PAPER NUMBER

2621

DATE MAILED: 03/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/771,585

Applicant(s)

DIETZ ET AL.

Examiner

Patrick L. Edwards

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 11 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-3 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10-11-2005 has been entered.

### ***Response to Arguments***

2. Applicant's arguments filed on 10-11-2005 have been fully considered. A response to these arguments is provided below.

## **Prior Art Rejections**

### **Summary of Argument:**

Applicant alleges that "Green does not disclose the use of thresholding to improve the detection of particles in a sample, as claimed. Rather, Green uses thresholding for the different purpose of classifying a sample region into one of a number of categories."

### **Examiner's Response:**

Applicant's arguments have been fully considered but are moot in view of the new grounds of rejection provided below.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim recites "calculating a threshold for particle detection in said composite image independently in each set of source pixel values." This limitation is internally contradictory because a threshold which is calculated "in said composite image" cannot also be calculated "independently in each set of source pixel values." Part (c) of the claim clearly recites that the composite image is generated by summing the sets of source pixel values. Thus, any threshold calculated in this composite image corresponds to each set of source pixels, and cannot also be calculated independently in each set of source pixels. The limitation in part (d) is therefore repugnant to the limitation in part (c).

This same analysis applies to part (e) of the claim, since it also attempts to do an action (particle detection) in both the composite image and independent sets of source pixels.

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For examination purposes, part (d) will be interpreted simply as “calculating a threshold for particle detection in said composite” since the phrase “independently in each set of source pixels” cannot be reconciled with the remaining limitations. Part (e) will be interpreted as “performing particle detection in said composite image using said threshold” since the phrase “independently in each set of source pixel values using the corresponding threshold” cannot be reconciled with the remaining limitations.

*Claim Rejections - 35 USC § 102*

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claim 2 is rejected under 35 U.S.C. 102(b) as being anticipated by Sizto et al. (USPN 5,556,764) (Sizto). Sizto discloses:

(a) **scanning the fixed volume capillary containing the sample to generate a plurality of channels of data, wherein each channel of data comprises a distinct detectable characteristic and a distinct background characteristic** (Sizto col. 2 lines 30-52: The reference describes scanning the fixed voluming capillary containing the sample (lines 30-34) to generate plural channels of data (line 48). The reference further describes that each channel of data comprises distinct, detectable characteristics (col. 2 lines 53-56). The reference further describes that each channel comprises a distinct background characteristic (col. 3 lines 59-61).).

(b) **sampling each of the channels of data to produce corresponding sets of pixel values** (Sizto col. 8 lines 59-63: The reference describes sampling the scanned data (with each scanned image corresponding to a data channel) to produce sets of pixel values.).

(c) **summing the sets of source pixel values to generate a composite image** (Sizto col. 9 lines 59-61).

(d) **calculating a threshold for particle detection in said composite image** (Sizto col. 14 lines 35-58 in conjunction with Figure 12: The reference describes using a calculated threshold for particle detection in a composite image.).

(f) **identifying, for each particle identified in a particular set of source pixels, the corresponding pixels in the remaining sets of source pixels** (Sizto col. 15 lines 6-30: The reference describes using a linear regression analysis to identify the coordinates of an identified pixel in image 1 and image 2 (i.e. remaining sets of source pixels).).

(g) **analyzing the identified pixels and calculating at least one of: (i) a volume of the sample scanned; and (ii) an absolute particle count** (Sizto col. 15 lines 35-36; col. 2 lines 49-53: The reference describes counting the target cells (i.e. an absolute particle count).).

*Claim Rejections - 35 USC § 103*

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sizto et al. (USPN 5,556,764) (Sizto) in view of Green (USPN 3,999,047).

regarding claim 1:

Sizto discloses (a) **scanning the fixed volume capillary containing the sample to generate a plurality of channels of data, wherein each channel of data comprises a distinct detectable characteristic and a distinct background characteristic** (Sizto col. 2 lines 30-52: The reference describes scanning the fixed voluming capillary containing the sample (lines 30-34) to generate plural channels of data (line 48). The reference further describes that each channel of data comprises distinct, detectable characteristics (col. 2 lines 53-56). The reference further describes that each channel comprises a distinct background characteristic (col. 3 lines 59-61).).

Sizto further discloses (b) **sampling each of the channels of data to produce corresponding sets of pixel values** (Sizto col. 8 lines 59-63: The reference describes sampling the scanned data (with each scanned image corresponding to a data channel) to produce sets of pixel values.).

Regarding part (c), Sizto fails to expressly disclose **independently modifying each set of pixel values to selectively enhance spatial features that are indicative of a target particle**. Green, on the other hand, is in the same environment as Sizto and discloses generating sets of enhanced pixel values by independently modifying each set of of pixel values to selectively enhance spatial features indicative of a target particle (Green col. 10 lines 27-57: The Green reference discloses spatially filtering each set of pixels. This spatial filtering as disclosed in Green is analogous to “generating sets of enhanced pixel values” as recited in the claim). It would have been obvious to one reasonably skilled in the art at the time of the invention to add Green’s spatial feature enhancement of independent channels to Sizto’s particle detection method. Such a modification would have allowed for a way of cleaning up a noisy signal to increase the effectiveness of subsequent particle detection (Green col. 10 lines 58-68).

Sizto discloses (d) **removing, from one or more sets of pixel values, the distinct background characteristics for the corresponding channel** (Sizto col. 3 lines lines 25-27; col. 4 lines 30-31; col. 10 lines 21-29; col. 12 lines 23-35; col. 13 lines 11-20; col. 13 lines 43-46; col. 15 line 42: The reference describes determining a background index (background characteristics) for each channel, and then removing the background index in order to define a region for cell characterization.). In Figure 10, the reference shows how the background noise terms for each channel are calculated.).

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Sizto discloses **(h) characterizing the target particles in the sample by analyzing the identified pixels and calculating at least one of: (i) a volume of the sample scanned; and (ii) an absolute particle count** (Sizto col. 15 lines 35-36; col. 2 lines 49-53: The reference describes counting the target cells (i.e. an absolute particle count).).

Parts (e)-(g) call for a method of establishing threshold values and detecting particles with those threshold values. Sizto discloses a method for establishing threshold values and using those threshold values to detect particles, but does not expressly disclose the details of this method in quite the same manner as they are set forth in steps (e)-(g). Green, on the other hand, is in the same environment as Sizto and does disclose these steps.

Green discloses (e) independently establishing threshold values for the detection for each set of enhanced pixel values (Green col. 5 lines 36-37 and col. 9 lines 38-44: The first cited passage discloses histogramming as a way to calculate thresholds. The second cited passage shows that these thresholds are indeed calculated independently in each set of source pixel values (i.e. each digitized channel)).

Green further discloses (f) independently identifying, in each set of enhanced pixel values, groups of above-threshold pixels located in patterns that are diagnostic of said particles (Green col. 5 line 45 – col. 6 line 6).

Green further discloses (g) independently identifying, for each group of above-threshold pixels located in a diagnostic pattern in a particular set of enhanced pixel values, the corresponding below-threshold or at-threshold pixels in the remaining sets of enhanced pixel values (Green col. 9 lines 45-63).

It would have been obvious to one reasonably skilled in the art at the time of the invention to modify Sizto's method for threshold determination and subsequent particle detection by employing a threshold calculation method that can be performed independently in each channel as taught by Green. It would also have been obvious in view of Green, to use this independent threshold to perform particle detection independently on each channel. Such a modification would have allowed for the separation of an image into a number of data sets without requiring the normal procedure of chromaticity coordinate calculations and subsequent complicated pattern recognition data processing (Green col. 6 lines 22-28). Therefore, this would have made for a more efficient and streamlined system that was less computationally intensive.

Regarding the final paragraph of the claim, which starts "wherein particles are...." This paragraph is redundant of parts (e)-(d) discussed above. Thus the above discussion is incorporated herein.

**regarding claim 3:**

Sizto discloses **(a) scanning the fixed volume capillary containing the sample to generate a plurality of channels of data, wherein each channel of data comprises a distinct detectable characteristic and a distinct background characteristic** (Sizto col. 2 lines 30-52: The reference describes scanning the fixed voluming capillary containing the sample (lines 30-34) to generate plural channels of data (line 48). The reference further describes that each channel of data comprises distinct, detectable characteristics (col. 2 lines 53-56). The reference further describes that each channel comprises a distinct background characteristic (col. 3 lines 59-61).).

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Sizto discloses **(b) sampling each of the channels of data to produce corresponding sets of pixel values** (Sizto col. 8 lines 59-63: The reference describes sampling the scanned data (with each scanned image corresponding to a data channel) to produce sets of pixel values.).

Sizto discloses **(e) calculating at least one of: (i) a volume of the sample scanned; and (ii) an absolute particle count** (Sizto col. 15 lines 35-36; col. 2 lines 49-53: The reference describes counting the target cells (i.e. an absolute particle count).).

**Regarding parts (c) and (d):** Sizto discloses calculating a threshold for particle detection, and then performing particle detection based on that threshold. However, Sizto fails to expressly disclose that the particle detection threshold is calculated independently in each set of source pixel values without first summing the source images. It follows that Sizto fails to expressly disclose using this threshold to perform particle detection independently in each set of source pixel values.

Green, on the other hand, discloses calculating the threshold for particle detection independently in each set of source pixel values (Green col. 5 lines 36-37 and col. 9 lines 38-44: The first cited passage discloses histogramming as a way to calculate thresholds. The second cited passage shows that these thresholds are calculated independently in each set of source pixel values (i.e. each digitized channel)). Green further discloses performing particle detection independently in each set of source pixels values using the corresponding threshold (Green col. 5 line 45 – col. 6 line 6). It would have been obvious to one reasonably skilled in the art at the time of the invention to modify Sizto's method for threshold determination and subsequent particle detection by employing a threshold calculation method that can be performed independently in each channel as taught by Green. It would also have been obvious in view of Green, to use this independent threshold to perform particle detection independently on each channel. Such a modification would have allowed for the separation of an image into a number of data sets without requiring the normal procedure of chromaticity coordinate calculations and subsequent complicated pattern recognition data processing (Green col. 6 lines 22-28). Therefore, this would have made for a more efficient and streamlined system that was less computationally intensive.

### *Conclusion*

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick L Edwards whose telephone number is (571) 272-7390. The examiner can normally be reached on 8:30am - 5:00pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joe Mancuso can be reached on (571) 272-7695. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

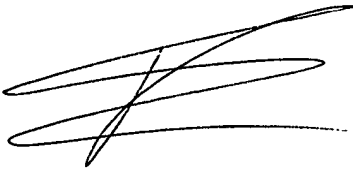
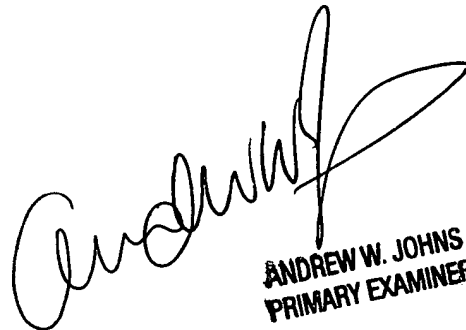
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Patrick L Edwards

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A handwritten signature consisting of several overlapping, horizontal, wavy lines.A handwritten signature in cursive script, appearing to read 'Andrew W. Johns'.

**ANDREW W. JOHNS  
PRIMARY EXAMINER**